

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

June 5, 2013

DP BARCODE(s): 403477, 401567

MRID(s) : 48858402
48858403

SUBJECT: Tefcite
(Name of Product)

FILE SYMBOL: 89101-R

DOCUMENT TYPE: Product Chemistry Review: Particle Size Distribution

Manufacturing-use [] OR End-use Product [X]

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
025601	1317-39-1	Cuprous oxide
072501	7440-22-4	Silver
129015	7440-66-6	Zinc

TEST LAB: Particle Technology Labs

SUBMITTER: Reintjes Marine Surface technologies, LLC

GUIDELINE: OCSPP 830.7520 Particle size, Fiber Length, and Diameter
Distribution

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

DATE APPROVED: June 5, 2013

COMMENT:

PDF ✓
5/14/13

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Office of Pesticide Programs

Antimicrobials Division (AD)

June 5, 2013

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA File Symbol. 89101-R
Product Name: Tefcite
DP Barcode(s): 403477, 401567

CODE: (A490) New Use Outdoor Non Food

DATE DUE: July 10, 2013

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Reintjes Marine Surface Technologies, LLC

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Cuprous oxide	58.000
Silver	0.018
Zinc	0.054
<u>Other Ingredients</u>	<u>41.928</u>
Total:	100.000

BACKGROUND:

Walter G. Talarek, PC as the agent for Reintjes Marine Surface Technologies, LLC has submitted data to support the registration of their new product called "Tefcite" EPA File Symbol 89101-R. This product is a thermoplastic antifouling powder to prevent hard and soft fouling on all boat/ship hulls/bottoms and stationary structures in fresh and salt water. The product is formulated using a combination of two EPA registered sources: Cuprous oxide and a Zinc Silver Zeolite.

This product chemistry review is to specifically address the evaluation of particle size distribution studies provided by the registrant at the Agency's request.

The data package contains two particle size distribution studies. The first (MRID# 48858402) is a study performed on the final product formulation. The second (MRID# 48858403) was performed on one source of the silver and zinc active ingredients which is supplied in the form of a powder.

MRID#	Study Title
48858402	Kopesky, W. (2012) Product Chemistry: Particle Size and Diameter Distribution: Tefcite. Project Number: 24839. Unpublished study prepared by Particle Technology Labs, Ltd. 5p.
48858403	Kopesky, W. (2012) Product Chemistry: Particle Size and Diameter Distribution of Iraguard B5000. Project Number: 24951. Unpublished study prepared by Particle Technology Labs, Ltd. 6p.

FINDINGS:

1. MRID 48858403 Performed on "Iraguard B5000", the source product of Silver and zinc active ingredients.
 - a. Instrument: Beckman Coulter "LS Particle Size Analyzer"
 - b. Carrier Liquid: Water
 - c. Optical model: Stdpids001.rfd PIDS Included
 - d. Other: No other pre or post analytic procedural steps or operational parameters were described in the report.
 - e. Report: The report consists of an image of a particle size distribution with Particle Diameter (um) on the X-axis and Volume (%) on the Y-axis. The image is of three separate populations of particles.

Population	Range Population Size (um)	Population Peak Particle Volume(um)	% of Product Particulates
1	0.046 -0.69	0.3	85.6
2	1.45-2.59	1.92	2.6
3	4.88-55.13	6.45	11.2
Comments	*13.9% of Population 1 less than 0.1 um		

2. MRID 48858402 Performed on "Tefcite Powder" includes the above Irgaguard B5000 material in its formulation.
- a. Instrument: "Malvern Mastersizer 2000" Accessory: Hydro 2000S (A)
 - b. Carrier Liquid:(Dispersant) Isopropyl Alcohol
 - c. Optical model: Not specified
 - d. Other: No other pre or post analytic procedural steps or operational parameters were described in the report.
 - e. Report: The report consists of an image of a Particle Size Distribution with Particle Size (um) on the X-axis and Volume (%) on the Y-axis. The image is of two separate populations of particles.
 - f.

Population (peak)	Range (µm)	Approximate Peak	% of Product
1	0.25-20.0	13 µm	20.7
2	20-126	63 µm	79.3
Comments	Neither population of particulates found in this product were less than 0.1 µm		

Comments:

1. The particle size determinations provided to support the registration of this product were each performed using the same general principles (dynamic light scattering) however they were performed using different instruments. Consequently it is difficult to draw definitive conclusions.
2. Both for the final product formulation and the silver-zinc zeolite source demonstrate there are two or more distributions evident which may represent different subpopulations of particulates. Such subpopulations may actually be the result of differently distributed materials that are mixed together in a formulation as well as the formation of populations of non aggregated vs aggregated particles.
3. The silver and zinc contained within the silver-zinc-zeolite source material have been considered as being ionic. If this is the case, the smaller sized particles found by the registrant in this source might more reasonably be considered as smaller particulates of the zeolite substance rather than elemental silver or zinc. It may be possible they represent other silver or zinc compounds that could have formed or incompletely formed zeolite compounds which are smaller in size. The data at hand does not allow for these distinctions to be accessed.

4. CTT feels that the particle size distribution on the silver-zinc zeolite performed using the Beckman Coulter "LS Particle Size Analyzer" may not be truly representative of that material as the shape of the distribution appears to lack definitive resolution and is likely to be artifact. The distribution is decidedly different from analysis performed on the same source provided by the producer of that material.
5. Few of the smaller particulates observed in the silver-zinc zeolite are apparent in the Tefcite product.
6. In all cases the chemical identity and physical properties of the populations described in these distributions are were not determined.